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PHILIPS

K010435

Philips Medical Systems

510(k) Summary

Company name:	Philips Medical Systems North America Company
Address:	710 Bridgeport Avenue, Shelton, CT 06484
Contact person:	Peter Altman
Telephone number:	203-926-7031
Prepared:	December 18, 2000
Device name:	Philips BV Pulsera/Endura
Classification name:	Mobile X-Ray System (90IZL), Class II, 21 CFR 892.172
Common/Usual name:	Mobile C-Arm Fluoroscopic System
Predicate Device(s):	Philips BV300 Series (Release 2.1)

Intended use:

The Philips BV Pulsera/Endura systems are Mobile C-Arm X-Ray Systems offering Radiographic and Fluoroscopic techniques in a wide variety of applications. The series has been designed primarily for use in the operating theater. The Philips BV Endura systems are intended for the same applications as the BV300 Series Release 2.1 systems, i.e. surgical interventions needing X-ray imaging and/or guidance and interventions inside and outside the Operating Room.

The Philips BV Pulsera systems are intended for the same applications as the BV300 Series Release 2.1 systems, i.e. surgical interventions needing X-ray imaging and/or guidance and interventions inside and outside the Operating Room and extended to include cardiac and advanced vascular applications.

System description:

The Philips BV Pulsera/Endura systems are Mobile C-Arm X-Ray Systems offering Radiographic and Fluoroscopic techniques in a wide variety of applications.

Substantial equivalence Information

The BV Pulsera/Endura systems are modifications of, and substantially equivalent to, the BV 300 Series, Release 2.1, 510(k) No. K982706.

Safety Information

The BV Pulsera/Endura systems comply with the applicable portions of 21 CFR parts 1020.30/.31/.32 and voluntary safety standards, such as UL 2601. The Information for Users contains comprehensive information to insure safe and effective use.

Philips Medical Systems
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 2 2001

Mr. Peter Altman
Director of Regulatory Affairs
Philips Medical Systems North America Company
710 Bridgeport Avenue
P.O. Box 860
SHELTON CT 06484-0917

Re: K010435
Philips BV Pulsera/Endura
Dated: February 12, 2001
Received: February 13, 2001
Regulatory Class: II
21 CFR §892.1650
Procode: 90 JAA, 90 IZL, and 90 IXL

Dear Mr. Altman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

David A. Segerson

David A. Segerson
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): _____

Device Name : **Philips BV 300 Series, Release 2.1**

Indications For Use :

The Philips BV Pulsera/Endura systems are Mobile C-Arm X-Ray Systems offering Radiographic and Fluoroscopic techniques in a wide variety of applications. The series has been designed primarily for use in the operating theater.

The Philips BV Endura systems are intended for the same applications as the BV300 Series Release 2.1 systems, i.e. surgical interventions needing X-ray imaging and/or guidance and interventions inside and outside the Operating Room.

The Philips BV Pulsera systems are intended for the same applications as the BV300 Series Release 2.1 systems, i.e. surgical interventions needing X-ray imaging and/or guidance and interventions inside and outside the Operating Room and extended to include cardiac and advanced vascular applications.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010435

Prescription Use √ OR Over-The-Counter Use _____
(Per 21 CFR 801.109

(Optional Format 1-2-96)